IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.	:	**10/679,763**
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Applicant	:	Barry M. Yomtov, et al.
Title	:	Medical Device for Neural Stimulation and Controlled Drug Delivery
TC/AU	:	3762
Examiner	:	Terri L. Smith
Docket No.	:	17509-0072
Customer No.	:	29052

AMENDMENT AND RESPONSE TO OFFICE ACTION

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Responsive to the Office Action mailed on February 21, 2006, please amend the application as follows and reconsider the application in view of the following remarks.

Amendments to the Specification begins on page **2** of this paper.

Amendments to the Drawings begins on page **5** of this paper.

The Claims are reflected in the listing of claims, which begins on page **6** of this paper.

Remarks begin on page **11** of this paper.

Submitted herewith are a Supplemental Information Disclosure Statement and a Petition for an Extension of Time for one month to June 21, 2006. The Commissioner is authorized to charge Deposit Account No. 19-5029 in the amount of to cover the $180.00 fee for consideration of the IDS and the $60.00 fee for a small entity for the petition for extension of time for responding to the office action.

Amendments to the Specification

Please amend the specification as follows:

At page 5, line 6, please insert the following new paragraphs:

--FIG. 5 is a perspective view of one embodiment of an implantable medical device that includes a catheter having drug-containing reservoirs at the distal end portion.

FIG. 6A is a plan view of one embodiment of the distal end portion of a catheter having an array of drug-containing reservoirs covered by reservoir caps that can be activated/opened using electrothermal ablation as described herein. FIG. 6B is a cross-sectional view of the device shown in FIG. 6A, taken along line B/B, and FIG. 6C is a cross-section view of the device, taken along line C/C.--

Please replace the paragraph beginning at page 9, line 10, with the following replacement paragraph:

The drug delivery device includes a substrate having a plurality of reservoirs, which contain the drug molecules for delivery. In one embodiment, the drug delivery module comprises a microchip drug delivery device. The substrate, reservoirs, reservoir caps, control circuitry, and power source are described at least in part herein and/or in U.S. Patents No. 5,797,898, No. 6,123,861, No. 6,551,838, No. 6,491,666, and No. 6,527,762, as well as U.S. Patent Application Publications No. 2002/0138067, No. 2002/0072784, No. 2002/0151776, and No. 2002/0107470. In one embodiment, control of reservoir cap opening includes electro-thermal ablation techniques, as described in U.S. Patent Application No. 10/641,507, filed August 15, 2003, published as U.S. Patent Publication No. 2004/0121486, which is incorporated herein by reference.

Please replace the paragraph beginning at page 24, line 6, with the following replacement paragraphs:

In one embodiment, a drug delivery module includes a catheter which can be inserted into the tissue lumen or structure of interest and which has one or more drug-containing reservoirs fabricated therein, for example at a distal portion of the catheter. ~~The body of the catheter serves as the substrate in which tens or hundreds of micro-reservoirs are arrayed around the catheter body at the distal tip portion.~~ **FIG. 5** illustrates one embodiment of a medical device **50** which includes a catheter **52** which can be inserted into the tissue lumen or structure of interest and which has one or more drug-containing reservoirs **54** fabricated therein, for example at a distal portion **53** of the catheter. The body of the catheter serves as the substrate in which the reservoirs are fabricated, for example using soft lithography or other techniques known in the art. For example, tens or hundreds of micro-reservoirs could be arrayed around the catheter body at the distal tip portion. The reservoirs are hermetically sealed by conductive reservoir caps, which are electrically connected to a power source and can be disintegrated by electrothermal ablation as described herein. Advantageously, the power source and control hardware **56** can be located at a proximal end of the catheter **55**, so they need not fit into or be located at the delivery site. The electrical traces could be built into the catheter body or supported on an inner or outer surface of the catheter body. **FIGS. 6A-C** illustrates a catheter tip portion **60** which has reservoirs **62** is substrate/catheter body **64**, wherein the reservoirs contain therapeutic agent **65** and are covered by conductive reservoir caps **66**, each of which are connected to input and output electrical leads **68** and **69**, respectively. See U.S. Patent Application No. 2002/0111601, which disclosed ~~one~~ another embodiment of a catheter type implantable medical device, ~~but which~~ one that utilizes a different reservoir opening technology than the electrothermal ablation system described herein.

Optionally, the catheter can have an internal fluid passageway extending between a proximal end portion and a distal end portion. The fluid passageway can be in communication with an infusion pump and a reservoir (e.g., a refillable reservoir containing a therapeutic fluid), so that the device can deliver a therapeutic fluid through the passageway to the delivery site. In

one embodiment, the pump is placed abdominally in a subcutaneous pocket, and the catheter is inserted into the intrathecal space of the spine, tunneled under the skin and connected to the pump. Such an embodiment could be used, for example, in the management of chronic pain or for spasticity therapy. The microarray of drug-containing reservoirs can be provided (i) on or in the body of the catheter, (ii) in a substrate device that is located at the proximal end of the catheter and releases drug into an infusion fluid pumped across the microarray openings to form a fluid/drug mixture that is pumped through the fluid passageway of the catheter, or (iii) in a combination of these. In one embodiment, the distal tip portion of the catheter includes one or more biological sensors to detect patient conditions that indicate the desirability or need for drug release. The sensors could extend from or be on the surface of the tip portion of the catheter body or could be located within one or more reservoirs. In one version, the device could include one catheter having a sensor on the distal end portion for implantation at a first site *in vivo*, and a second catheter having drug-containing reservoirs on the distal end portion for implantation at a second site *in vivo*.

Amendments to the Drawings

New Figures 5 and 6A-C have been added. A new sheet for these figures is appended hereto.

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) A medical device for electrical stimulation of neural tissue and controlled drug delivery comprising:

an implantable drug delivery module which comprises

a plurality of reservoirs,

a release system contained in each of the reservoirs, wherein the release system comprises at least one drug, ~~and a control means for selectively releasing a pharmaceutically effective amount of the drug from each of the reservoirs;~~

a plurality of discrete reservoir caps separating the release system from an environment outside of the reservoirs, and

means for disintegrating one or more of the reservoir caps by electrothermal ablation to release the at least one drug from one or more of the reservoirs;

a neural electrical stimulator which comprises

a signal generator, and ~~connected to~~

at least one stimulation electrode for operable engagement with a neural tissue of a patient, wherein the at least one stimulation electrode is connected to the signal generator; and

at least one microcontroller for controlling operational interaction of the drug delivery module and the neural electrical stimulator.

2. (Currently Amended) The medical device of claim 1, wherein the at least one microcontroller controls both the signal generator and the ~~control~~ means for disintegrating one or more of the reservoir caps of the drug delivery module.

3. (Currently Amended) The medical device of claim 1, further comprising a power source operably connected to the means for disintegrating one or more of the reservoir caps, the neural electrical stimulator, the at least one microcontroller, or a combination thereof.

4. (Withdrawn) The medical device of claim 1, wherein the stimulation electrode is on an outer surface of a hermetically sealed encasement containing the drug delivery module and microcontroller.

5. (Currently Amended) The medical device of claim 1, ~~wherein the stimulation electrode extends a distance from~~ further comprising a hermetically sealed encasement containing the drug delivery module and microcontroller, wherein the stimulation electrode extends a distance from the hermetically sealed encasement.

6. (Currently Amended) The medical device of ~~claim 4~~ claim 5, wherein a flexible catheter connects the stimulation electrode to the encasement.

7. (Currently Amended) The medical device of claim 1, ~~wherein~~ further comprising telemetry components in operable communication with the microcontroller.

8. (Withdrawn) The medical device of claim 1, wherein the neural electrical stimulator is provided as a module separate from the drug delivery module.

9. (Withdrawn) The medical device of claim 8, wherein the neural electrical stimulator module is implantable.

10. (Withdrawn) The medical device of claim 8, wherein the drug delivery module is controlled by a telemetry or hard-wired signal from the stimulator module.

11. (Withdrawn) The medical device of claim 8, comprising two microcontrollers, one of which controls the stimulator module and the other which controls the drug delivery module.

12. (Currently Amended) The medical device of claim 1, ~~for treating~~ adapted to treat chronic pain in a patient.

13. (Currently Amended) The medical device of claim 1, ~~for treating~~ adapted to treat a movement disorder in a patient.

14. (Currently Amended) The medical device of claim 1, ~~for treating~~ adapted to treat incontinence in a patient.

15. (Currently Amended) The medical device of claim 1, ~~for treating~~ adapted to treat obesity in a patient.

16. (Currently Amended) The medical device of claim 1, ~~for controlling~~ adapted to control seizures in a patient.

17. (Original) The medical device of claim 1, wherein the drug delivery module comprises a microchip drug delivery device.

18-19. (Cancelled).

20. (Original) The medical device of claim 1, further comprising one or more sensors operable to deliver a signal to the microcontroller.

21. (Original) The medical device of claim 20, wherein the one or more sensors control release of the drug from the drug delivery module and control generation of an electrical current from the neural stimulator to neural tissue.

22. (Original) The medical device of claim 1, wherein the drug is an analgesic, an anti-anxiety agent, an anti-incontinence agent, a skeletal muscle relaxant, an anti-convulsant, or an anti-parkinson agent.

23. (Currently Amended) A method of treating a patient comprising delivery of an electrical signal and at least one drug to a patient in need thereof comprising:

implanting into the patient the implantable drug delivery module of the medical device of claim 1;

bringing the stimulator electrode into operable engagement with a neural tissue of the patient;

activating the signal generator to deliver electrical stimulation from the stimulator electrode to the neural tissue of the patient; and

releasing the drug from ~~the reservoir~~ one or more of the reservoirs into the patient.

24. (Original) The method of claim 23, wherein the drug and the electrical neural stimulation are delivered simultaneously.

25. (Original) The method of claim 23, wherein the drug is delivered intermittently or continuously.

26. (Original) The method of claim 23, wherein the electrical stimulation is delivered intermittently or continuously.

27. (Original) The method of claim 23, wherein the drug is released before the electrical neural stimulation and is effective to reduce the stimulation threshold of the neural tissue.

28. (Original) The method of claim 23, wherein release of the drug is alternated with the delivery of the electrical stimulation.

29. (Withdrawn) The method of claim 23, wherein the neural electrical stimulator is provided as a module separate from the drug delivery module.

30. (Withdrawn) The method of claim 29, further comprising implanting the neural electrical stimulator into the patient.

31. (Currently Amended) The method of claim 23, which is used to treat ~~for treating~~ chronic pain in the patient.

32. (Currently Amended) The method of claim 23, which is used to treat ~~for treating~~ a movement disorder in the patient.

33. (Currently Amended) The method of claim 23, which is used to treat ~~for treating~~ incontinence in the patient.

34. (Currently Amended) The method of claim 23, which is used to treat ~~for treating~~ obesity in the patient.

35. (Currently Amended) The method of claim 23, which is used to control ~~for treating~~ seizures in the patient.

36. (New) The medical device of claim 1, wherein the implantable drug delivery module comprises a catheter or tube, the plurality of reservoirs being located proximate to an end of the catheter or tube.